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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,549	08/03/2001	Jeffrey C. Rapp	AVI 013	1388

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AVIGENICS, INC.
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EXAMINER
WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/11/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/922,549	RAPP, JEFFREY C.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-61 is/are pending in the application.

4a) Of the above claim(s) 58-61 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The abstract of the disclosure is objected to because it is greater than 250 words. Correction is required. See MPEP § 608.01(b).

Claims 1-61 are pending and under consideration in the instant office action.

Claims 58-61 will not be considered because they are so unclear. The claims are directed toward an isolated nucleic acid having a codon complement optimized for protein expression in an avian. But it is unclear what applicants consider a codon complement, what codon complements are optimized for protein expression in an avian, or what applicants consider optimal protein expression in an avian. It is noted that applicants definition of "complementary" (pg 22, line 1) describing the relationship between two nucleic acids cannot be extrapolated to a codon complement which appears to be one nucleic acid. The structure and function of the nucleic acid being claimed cannot be envisioned. Therefore, claims 58-61 will not be considered.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-33, drawn to an isolated nucleic acid sequence comprising an avian lysozyme gene expression control region, classified in class 536, subclass 24.1.

II. Claims 34-36, drawn to a method of expressing a heterologous polypeptide in a host cell *in vitro*, classified in class 435, subclass 455.

III. Claims 34-36, drawn to a method of expressing a heterologous polypeptide in a host cell *in vivo*, classified in class 514, subclass 44.

IV. Claims 37-39 and 41-44, drawn to a eukaryotic cell transformed *in vivo* with an expression vector, classified in class 435, subclass 325.

V. Claims 37-40 and 42-44, drawn to a eukaryotic cell transformed *in vitro* with an expression vector, classified in class 435, subclass 325.

VI. Claims 45-57, drawn to a transgenic avian, classified in class 800, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II or III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used to transfect cells *in vitro* or to make transgenic avians. Methods of transfecting cells *in vitro* and methods of making transgenic avians are patentably distinct for reasons discussed below in comparing Groups II and III.

Inventions I and IV or V are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful to

transfect cells *in vitro* or to make transgenic avians and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions I and VI are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful to make recombinant cells *in vitro* and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as being used together because cells are not transfected *in vitro* then used to make transgenic avians. The inventions also have different functions and different effects because exogenous protein secreted by cells *in vitro* can be used in assays and is harvested from the media while exogenous protein secreted by cells transfected *in vivo* can be used to alter the avian and isolated from the egg white or other body tissue.

Inventions II or III and IV or V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to make a transgenic avian or to transfect cells *in vitro*. The transformed cell can be made by transfecting cells *in vitro* or *in vivo* which are materially distinct processes as discussed below in the comparison of Groups IV and V.

Groups II and VI are patentably distinct because the cell transfected *in vivo* is used to make a transgenic avian while the transgenic avian is used to isolate exogenous protein from the egg white. The protocols and reagents for cells and avians are patentably distinct.

Groups III and VI are patentably distinct because the cell transfected *in vitro* is used to isolate exogenous protein from media in culture while the transgenic avian is used to isolate exogenous protein from the egg white. The protocols and reagents

required to make and use cells transfected *in vitro* and transgenic avians are materially distinct and separate. The cell transfected *in vitro* is not required to make the transgenic avian and the transgenic avian is not required to make the cell transfected *in vitro*.

Groups IV and V are patentably distinct because the cell transfected *in vitro* is used to isolate exogenous protein from media in culture while the cell transfected *in vivo* is used to make transgenic avians and isolate exogenous protein from the egg white. The protocols and reagents required to make and use cells transfected *in vitro* and *in vivo* are materially distinct and separate. The cell transfected *in vitro* is not required to make the cell transfected *in vivo* and vice versa.

Groups IV and VI are patentably distinct because the cell transfected *in vivo* is used to make transgenic avians while the transgenic avians are used to isolate exogenous protein from the egg white. The protocols and reagents required to make and use cells transfected *in vivo* and transgenic avians are materially distinct and separate.

Groups V and VI are patentably distinct because the cell transfected *in vitro* is used to isolate exogenous protein from media in culture while the transgenic avians is used to isolate exogenous protein from the egg white. The protocols and reagents required to make and use cells transfected *in vitro* and transgenic avians are materially distinct and separate. The cell transfected *in vitro* is not required to make the transgenic avian and the transgenic avian is not required to make the cells transfected *in vitro*.

Applicants must also elect one of the following patentably distinct nucleic acid sequences for consideration:

A) SEQ ID NO: 67,

B) SEQ ID NO: 68,

C) SEQ ID NO: 66, or

D) SEQ ID NO: 65.

The nucleic acid sequences of A), B), C), and D) are patentably distinct because they have different structures and different functions. The burden required to search A), B), C), and D) together would be undue. Failure to elect one of the patentably distinct nucleic acid sequences for consideration in addition to electing one of the patentably distinct Groups (I-VI) above will be considered non-responsive.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is 703-305-0120. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

308-4242 for regular communications and 703-308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MICHAEL C. WILSON
PATENT EXAMINER